

APR 26 2001

K002973
EMBOL-X

510(k) SUMMARY

SUBMITTER'S NAME: EMBOL-X[®], Inc.

ADDRESS: 645 Clyde Ave, Mountain View CA 94043-2208

PHONE NUMBER: (650) 390-0280

FAX NUMBER: (650) 390-0282

CONTACT PERSON: Ed Lee

DATE PREPARED: September 20, 2000

TRADE NAME: EMBOL-X[®] Introducer

COMMON NAME: Introducer

CLASSIFICATION NAME: Introducer, Catheter

PREDICATE DEVICE: Cordis[®] Catheter Sheath Introducer

DEVICE DESCRIPTION: The EMBOL-X Introducer consists of a single lumen housing with a hemostasis gasket and a removable self-venting snap-lock Obturator. It contains a flange for suture attachment. The EMBOL-X Introducer is 17 FR (5.7mm) at its distal tip. It can accommodate the introduction of intravascular devices ranging from 12 FR – 14 FR in size.

INTENDED USE: The EMBOL-X Introducer is indicated for use in arterial and venous procedures requiring the introduction of intravascular devices.

TECHNOLOGICAL CHARACTERISTICS COMPARISON: As with the predicate device, the EMBOL-X Introducer is substantially equivalent having a single lumen housing for the introduction of intravascular devices and an internal hemostasis gasket to minimize backbleeding.

BIOCOMPATIBILITY: All materials used in the EMBOL-X Introducer are biocompatible.

PERFORMANCE TESTS: In-vitro bench test results for joint strength and gasket seal integrity were substantially equivalent or better than in performance to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 26 2001

Mr. Edwin Lee
Embol-X®, Inc.
645 Clyde Avenue
Mountain View, CA 94043-2208

Re: K002973
Embol-X® Introducer
Regulatory Class: II (two)
Product Code: DYB
Dated: February 16, 2001
Received: February 20, 2001

Dear Mr. Lee:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

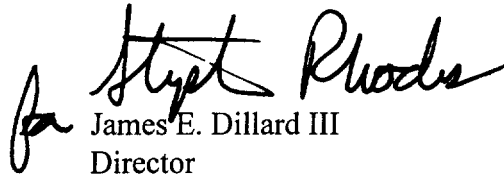
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further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "James E. Dillard III". The signature is written in a cursive style with a large, stylized "J" and "D".

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EMBOL-X

Ver/ 3 - 4/24/96

Applicant: EMBOL-X[®], Inc.

510(K) NUMBER (IF KNOWN): ~~NA~~ K002973


Device Name: EMBOL-X[®] INTRODUCER

Indications For Use:

The EMBOL-X[®] Introducer is indicated for use in arterial and venous procedures requiring the introduction of intravascular devices.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division of Cardiovascular & Respiratory Devices
510(k) Number K002973

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)